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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/464,416	12/16/99	THANAVALA	Y RPP:156BUS

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1651	5

DATE MAILED: 04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/464,416	Thanavala et al.
Examiner	**Group Art Unit**
Michele Flood	1651

☒ Responsive to communication(s) filed on *Dec 16, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The signature of the first inventor, Yasmin Thanavala, is missing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are made vague and indefinite by the phrase "providing an immune response" because the meaning of the phrase is unclear. Ambiguity exists in the identification or the process. In what way is an immune response provided in an animal? Is the claimed invention directed to a method of primary or secondary immunization? Or is the invention directed to a method of serial immunization? Does applicant intend protective immune response in the meaning

of "providing an immune response"? The lack of clarity makes the claims very vague and indefinite.

Claims 1 is made vague and indefinite by the phrase "in an animal made immunoreceptive to the NEPA"; and, Claim 3 is made vague and indefinite by the phrase "wherein the animal is made immunoreceptive to the NEPA" because the meaning of the phrases is unclear. Ambiguity exists in the identification of the process and it is uncertain as to what applicant intends to direct the invention. In what way is an animal made immunoreceptive to an antigen? It is uncertain whether the immune responsiveness of the animal is a preexisting condition or a newly required condition of immune responsiveness due to the feeding of the plant that contains the NEPA antigen. The lack of clarity makes the claims indefinite.

All of the claims are made vague and indefinite by the phrase "providing an immune response to a non-enteric pathogen" in line 1 of Claim 1, by the phrase "wherein the animal is made immunoreceptive to the NEPA in lines 1 and 2 of Claim 3, and by the phrase "renders the animal immunoreceptive to the NEPA" in line 3 of Claim 3 because it is unclear as to Applicant's meaning of the phrases. Therefore, it is uncertain as to what subject matter Applicant regards as the invention.

Regarding Claim 1, it appears that step in the claimed process is missing because it is not apparent how the animal is made immunoreceptive to the antigen. Was the animal made immunoreceptive by exposure to the antigen via a contaminated biological material, such as blood or mother's milk? Or, was the animal made immunoreceptive to the NEPA by artificial

immunization, such as a vaccine injection? There is no apparent difference in the terms "providing an immune response" or "made immunoreceptive", even in view of Applicant's definition of the terms, since immunoreceptive could mean the ability of an individual to demonstrate an immune response to an antigen upon exposure of the individual to the antigen. Thus, any animal with a health immune system is considered immunoreceptive. The lack of clarity makes the claims indefinite.

Regarding Claim 11, the term "*solanaceae*" should be replaced with "*Solanaceae*".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koprowski (A) in view of Stites (U).

Applicant claims a method for providing an immune response to a non-enteric pathogen antigen (NEPA), in an animal or a human made immunoreceptive to the NEPA, by feeding the animal or human with a substance comprising a physiologically acceptable plant material containing the NEPA and adjuvant from a plant that has been genetically altered to express said NEPA. Applicant further claims a therapeutic regimen thereof, comprising feeding the animal or human a potato from the family *Solanaceae*.

Koprowski teaches a process of providing an immune response in an animal or a human to a non-enteric pathogen, especially the non-enteric pathogen rabies street virus. In the process, a physiologically acceptable plant is genetically altered to express an antigen and used as an oral vaccine delivery system to feed the animal or human a non-enteric pathogen antigen. Routes of administration in the delivery of the substance comprising the plant material containing the NEPA are taught in Column 5, lines 43-61. In Column 7, lines 18-31, Koprowski teaches other viral, fungal, and bacterial pathogens which can be used against the invention. The vaccine or the plant material containing the non-enteric pathogen antigen can be administered to an individual with an adjuvant to facilitate or improve immunological activity. See Column 6, lines 33-36. In Column 8, lines 24-31, Koprowski teaches plant infecting microorganisms and solanaceous plant hosts, including potatoes. As detailed above, Koprowski teaches a method of inducing an immune response to a non-enteric pathogen antigen in an animal or a human by feeding the said subjects

plant material from a genetically altered plant that contains the NEPA. Koprowski does not teach a method wherein the immunoreceptive animal or immunoreceptive human is fed a substance comprising a physiologically acceptable material containing the NEPA, or a therapeutic regimen thereof.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional step to the process taught by Koprowski to provide an immune response in a non-enteric pathogen antigen immunoreceptive animal or human by feeding the said subjects a substance containing the NEPA because the art recognizes the routine practice of inducing immunity or an immune response in an animal or human that has either passive immunity, acquired immunity or actively acquired immunity which is demonstrated by an antibody response that may or may not relate to specific immunity to infection or disease by vaccination or artificial immunization to provide or elicit an immune response. Moreover, Stites teaches that reimmunization in a previously immune or immunoreceptive individual provides a rapid secondary increase in immunity. See page 724, Column 2, lines 1-42. Thus, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success that the feeding of an animal with plant material containing a NEPA in an immunoreceptive animal would provide an immune response. Moreover, one of ordinary skill in the art at the time the invention was made would have been motivated to optimize the teachings of Koprowski by inducing an immune response in a non-enteric pathogen immunoreceptive individual, comprising a therapeutic regimen of ingesting the said plant material in a plurality of different times and dose ranges

because Stites teaches, on pages 724, lines 28-32, that the timing of primary immunization, the interval doses, and the timing of reimmunization administrations are based on both theoretic considerations and vaccine administrations. Thus, one would have had a reasonable level of providing a therapeutic regimen such as the one in the claimed invention because the determination of an effective treatment method for providing an immune response in an immunoreceptive individual would have been a matter of routine optimization to one of ordinary skill in the art at the time the invention was made.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-2 and 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen (B) and Koprowski (A), and further in view of Stites (U).

Applicant claims a method for providing an immune response to hepatitis B surface antigen (HBSAG), in an animal or human made immunoreceptive to HBsAg, by feeding the animal or human with a substance comprising a physiologically acceptable plant material containing the HBsAg and adjuvant from a plant that has been genetically altered to express said HBsAg. Applicant further claims a therapeutic regimen thereof, comprising feeding the animal or human a potato from the family *Solanaceae.*

Arntzen teaches a method of making a genetically altered plant containing hepatitis B surface antigen. Arntzen teaches an anti-viral vaccine produced in physiologically acceptable plants and then administered through standard vaccine procedure or by feeding the plants to an

animal or human. Arntzen specifically teaches methods of making a transgenic potato plant expressing an immunogen derived from hepatitis B surface antigen, wherein the immunogen is capable of eliciting an immune response in an animal by consumption of the said plant material. Koprowski also teaches methods of making vaccines and physiologically acceptable edible plant material containing microbial, viral or fungal pathogenic antigens that can be used to provide an immune response in an animal or human. Koprowski teaches a method for genetically altering the plant material of solanaceous plants, in Column 8, lines 24-31. Koprowski teaches that the oral vaccines can further comprise an adjuvant. See Column 6, lines 33-36. As detailed above, both Koprowski and Arntzen teach methods of inducing an immune response to HBsAg in an animal or a human by feeding the said subjects plant material from a genetically altered plant that contains HBsAg. Neither Arntzen nor Koprowski teach a method comprising feeding a hepatitis B surface antigen immunoreceptive animal or human plant material comprising a potato from the family *Solanaceae* which has been genetically altered such that it contains HBsAg.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional step to the process taught by either Arntzen or Koprowski to provide an immune response in a HBSAG-immunoreceptive animal or human by feeding the said subjects a substance containing HBSAG because the art recognizes the routine practice of inducing immunity or an immune response in an animal or human that has either passive immunity, acquired immunity or actively acquired immunity which is demonstrated by an antibody response that may or may not relate to specific immunity to infection or disease by

vaccination or artificial immunization to provide or elicit an immune response. Moreover, Stites teaches that reimmunization in a previously immune or immunoreceptive individual provides a rapid secondary increase in immunity. See page 724, Column 2, lines 1-42. Thus, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success that feeding an HBsAg-immunoreceptive individual a solanaceous potato plant material containing HBsAg which further comprises an adjuvant would provide a positive immune response. Moreover, one of ordinary skill in the art at the time the invention was made would have been motivated to optimize the teachings of Arntzen by inducing an immune response in a HBsAg-immunoreceptive individual, comprising a therapeutic regimen of ingesting the said plant material in a plurality of different times and dose ranges because Stites teaches, on pages 724, lines 28-32, that the timing of primary immunization, the interval doses, and the timing of reimmunization administrations are based on both theoretic considerations and vaccine administrations. Thus, one would have had a reasonable level of providing a therapeutic regimen such as the one in the claimed invention because the determination of an effective treatment method for providing an immune response in an immunoreceptive individual would have been a matter of routine optimization to one of ordinary skill in the art at the time the invention was made.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Double Patenting

Claims 2 and 4 of this application conflict with claims 1 and 2 of Application No. 09/418,177 and Application No. 09/420,695. 37 CFR 1.78(b) provides that when two or more applications filed by the same applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 2 and 4 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of copending Application No. 09/418,177 and 09/420,695.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 09/464,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter, the scopes overlap and are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/420,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter, the scopes overlap and are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/418,177 Although the conflicting claims are not identical, they are not patentably distinct from

each other because the claimed inventions are directed to the same subject matter, the scopes overlap and are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-4932. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER

mcf

April 5, 2000